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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/091,172 | 03/04/2002 | Juan I. Perez | ENDOV-55674 | 9937 |

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EXAMINER

GILPIN, CRYSTAL M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3738

DATE MAILED: 07/15/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,172

Applicant(s)

PEREZ ET AL.

Examiner

Crystal M Gilpin

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner's Notes:

Page 8, Line 15 and Line 20: The word "endovascular" is written twice.

Page 9, Line 20: The word "sheath" is misspelled as -sehath-.

Specification

The disclosure is objected to because of the following informalities:

The reference to Item Number 901, on page 29 in -with a stainless steel tube 901 (Fig. 8).- is not shown in Figure 8.

Appropriate correction is required.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 7-9, 12, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (USPN 5,575,817).

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Regarding claims 1, 8 and 15, Martin discloses a system for treating vasculature at a repair site comprising a first treatment component (Figure 1, Reference Number 1), a first sheath or retractable membrane (Column 2, Lines 5-6) with a length sufficient to extend to a repair site and before being retracted, a first treatment component (Figure 1, Reference Number 7) and a loading capsule comprising the restraining sheath of the second section and a pusher assembly or catheter (Column 2, Lines 18-22) with an inner tube (Figure 3). Martin further discloses that the first sheath and the restraining sheath of the loading capsule are configured to mate (Column 2, Lines 22-30) and therefore have approximately equal outer profiles.

Regarding claims 2-4, Martin discloses that there is a plurality of subsequent treatment components (Figure 1, Reference Numbers 9 and 1) and that the first sheath is retracted to deploy the treatment components (Column 2, Line 15) after restraining the component in a compressed configuration (Column 4, Lines 8-10).

Regarding claim 5, Martin discloses that the treatment component is self-expanding (Column 2, Lines 38-40).

Regarding claim 7, Martin discloses the use of a guide wire (Figure 3, Reference Number 19).

Regarding claim 9, Martin discloses that the pusher assembly or catheter is capable of simultaneously engaging a plurality of treatment components (Column 2, Lines 4-6), where the first section comprises the upper limb, first lower limb and a portion of the second lower limb (Column 1, Lines 46-49).

Regarding claims 12 and 16, Martin discloses that the pusher assembly, used to advance treatment components includes an inner tube (See attached Figure 3- *text added by the Examiner*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (USPN 5,575,817).

Regarding claim 10, Martin discloses a treatment system that includes a pusher assembly, or catheter ((See attached Figure 3- *text added by the Examiner*), that has a tapered tip. Martin lacks the teaching of the tapered tip being flexible, however it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Martin to have a flexible pusher assembly tip to make navigation within the body lumen easier.

3. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (USPN 5,575,817) in view of Drasler et al. (USPN 6,451,051).

Regarding claim 11, Martin discloses a system for treating vasculature including restraining the first treatment component in a non-expanded form, however he lacks the teaching of cloverfolding the component. Drasler et al. teach of a foldable tubular endoprosthesis that can be cloverfolded (Figures 2C and 2D) so that it can be easily inserted into the vasculature in a compressed state. Therefore, it would have been obvious to one of ordinary skill in the art at the

time the invention was made to modify the invention of Martin to have the treatment component cloverfolded so that it can be entered into the vasculature in a compressed state.

4. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (USPN 5,575,817) in view of Snow et al. (USPN 6,299,622).

Regarding claims 13 and 14, Martin discloses a system for treating vasculature including a pusher assembly with an inner tube, where the inner tube has an inferior and superior end, however he lacks the teaching of an exit notch. Snow et al. teach of a catheter with an exit notch (Fig. 4, Reference Number 52) that is provided for excising material within a body lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Martin to have an exit notch for the purpose of excising harmful material in the body lumen before implanting the treatment components.

5. Claims 6 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (USPN 5, 575, 817) in view of Leonhardt et al. (USPN 5,713,917).

Regarding claims 6, 18, 22 and 23, Martin discloses a system for treating vasculature including a pusher assembly, a loading capsule that is capable of mating with an introducer sheath (Column 2, Lines 22-30), however he lacks the teaching of an introducer sheath and having the first treatment component inserted through the loading capsule. Leonhardt et al. teach of a method for engrafting a vessel that includes a sheath introducer, through which all components are introduced into the lumen, so that only one sheath is necessary during the deployment procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Martin to have the loading capsule mate with a single introducer sheath for the deployment of a plurality of graft components.

Regarding claim 19, Martin discloses that the first sheath and the restraining sheath of the loading capsule are configured to mate (Column 2, Lines 22-30) and therefore have approximately equal outer profiles.

Regarding claim 20, Martin discloses the use of a guide wire (Figure 3, Reference Number 19).

Regarding claim 21, Martin discloses that the treatment component is self-expanding (Column 2, Lines 38-40).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Crystal M Gilpin whose telephone number is 703-305-8122. The examiner can normally be reached on M-F, 9:00-5:00 (Second Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The group fax phone number for the organization where this application or proceeding is assigned are 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

cmg
July 11, 2003


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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FIG. 3

